K062525

SECTION 5: 510(k) SUMMARY

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Submitter:

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Contact:

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MAY 16 2007

Date of preparation: March 27, 2006

Name of device: *Trade/Proprietary Name: Reprocessed LigaSure Vessel Sealer/divider*

Classification Name: Electrosurgical cutting and coagulation device and accessories

Predicate Device	**510(k) Title**	**Manufacturer**
K031011	LigaSure™ 5mm Laparoscopic Sealer/divider	Valleylab, Inc.

Device description: The Vessel Sealer/divider is an electrosurgical instrument for use with the LigaSure™ Vessel Sealing Generator (not within the scope of this submission). The device is able to seal vessels, divide vessels and tissue clamped between its jaws, grasp tissue, and is capable of blunt dissection. The diameter of the shaft is 5mm and the working length is 37cm. Device controls are located on the instrument handle. The instrument is supplied sterile for single patient use.

Indications for Use: Reprocessed Vessel Sealer/dividers are bipolar electrosurgical instruments intended for use with the LigaSure Generator in general and gynecologic laparoscopic surgical procedures where ligation and division of vessels is desired. The instrument creates a seal by application of RF electrosurgical energy to vascular structures (vessels) interposed between the jaws of the instrument. A blade within the instrument is surgeon-actuated to divide tissue.

Indications for use include general laparoscopic procedures including urologic, vascular, thoracic and thoracoscopic, and gynecologic laparoscopic procedures where ligation and division of vessels is performed, including such procedures as laparoscopically assisted vaginal hysterectomy, Nissen fundoplication, colectomy, adhesiolysis, oophorectomy, etc.

The LigaSure 5mm Vessel Sealer-Divider can be used on vessels

up to and including 7mm diameter, and bundles of tissue as large as will fit in the jaws of the instrument.

Technological characteristics:

The design, materials, and intended use of Reprocessed Vessel Sealer/dividers are identical to the predicate devices. The mechanism of action of Reprocessed Vessel Sealer/Dividers is identical to the predicate devices in that the same standard mechanical design, materials, and size are utilized. There are no changes to the claims, intended use, clinical applications, patient population, performance specifications, or method of operation. In addition, Ascent Healthcare Solutions's reprocessing of Vessel Sealer/dividers includes removal of adherent visible soil and decontamination. Each individual Vessel Sealer/divider is tested for appropriate function of its components prior to packaging and labeling operations.

Performance data:

Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of Reprocessed Vessel Sealer/dividers. This included the following tests:

- Biocompatibility
- Validation of reprocessing
- Sterilization Validation
- Function test(s)
- Packaging Validation

Performance testing demonstrates that Reprocessed Vessel Sealer/dividers perform as originally intended.

Conclusion:

Ascent Healthcare Solutions concludes that the modified devices (Reprocessed Vessel Sealer/dividers) are safe, effective, and substantially equivalent to the predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ascent Healthcare Solutions
% Ms. Moira Barton
Regulatory Affairs Manager
10232 South 51st Street
Phoenix, Arizona 85044

MAY 16 2007

Re: K062525
Trade/Device Name: Reprocessed LigaSure Vessel Sealer/divider
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI, NUJ
Dated: April 2, 2007
Received: April 4, 2007

Dear Ms. Barton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K062525

SECTION 4: INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device Name: Reprocessed LigaSure Vessel Sealer/divider

Indications For Use: The Reprocessed 5 mm Vessel Sealer-Divider is a bipolar electrosurgical instrument intended for use with the LigaSure Generator in general and gynecologic laparoscopic surgical procedures where ligation and division of vessels is desired. The instrument creates a seal by the application of RF electrosurgical energy to vascular structures (vessels) interposed between the jaws of the instrument. A blade within the instrument is actuated to divide tissue.

Indications for use include general laparoscopic surgical procedures including urologic, vascular, thoracic and thoracoscopic, and gynecologic laparoscopic procedures where ligation and division of vessels is performed. These procedures include: laparoscopically assisted vaginal hysterectomy, Nissen fundoplication, colectomy, ad hesiolysis, oophorectomy, etc. The Reprocessed 5mm Vessel Sealer-Divider has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures, and should not be used for these procedures.

The Reprocessed 5mm Vessel Sealer-Divider can be used on vessels up to and including 7mm diameter, and tissue bundles as large as will fit in the jaws of the instrument.

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062525

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

To whom it may concern: K062525

- The predicate OEM device is LS1500 LigSure™ 5mm Laparoscopic Sealer/Divider (K031011) manufactured and distributed by Valleylab.

- The reprocessed device is "Reprocessed LS 1500 LigaSure 5mm Laparoscopic Sealer/Divider reprocessed by Ascent Healthcare Solutions